



State of California-Health and Human Services Agency  
**Department of Health Services**



ARNOLD SCHWARZENEGGER  
Governor

Date: October 17, 2006

N.L.: 11-1006  
Index: Benefits  
(Supercedes N.L.: 27-1005)

TO: ALL COUNTY CALIFORNIA CHILDREN SERVICES (CCS) PROGRAM  
ADMINISTRATORS, MEDICAL CONSULTANTS, AND STATE  
CHILDREN'S MEDICAL SERVICES (CMS) BRANCH STAFF

SUBJECT: PALIVIZUMAB (SYNAGIS™)

## **I. PURPOSE**

The purpose of this numbered letter, which supercedes N.L.:27-1005 is to update current CCS policy regarding the authorization of Palivizumab. Effective the date of this letter, the policy identified below supercedes the policy promulgated in N.L.:27-1005.

## **II. BACKGROUND**

Palivizumab (trade name Synagis) is a humanized monoclonal antibody produced by recombinant DNA technology licensed by the Federal Drug Administration and indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease.

Palivizumab is the agent of choice for monthly prophylaxis in most high-risk infants and children because of ease of intramuscular administration, safety, efficacy, and non-interference with the immune response to measles-mumps-rubella and varicella vaccines. Typically, November through April is considered RSV season, but it may occur earlier or persist later, depending on the community. Immunoprophylaxis against RSV is usually initiated at the beginning of November, and the last dose is administered at the beginning of March, providing protection into April. However, it is dependent upon the physician

requesting Palivizumab to determine when immunoprophylaxis begins and ends. In some instances, administration may begin as early as September.

A brief review of recent history of Palivizumab indicates that in December 2002, Medi-Cal expanded the Palivizumab policy of 1998 and issued Policy Statement 2002-12: "Addendum to Policy Statement 98-9: Palivizumab (Synagis™)" making Palivizumab a covered benefit as "prophylactic treatment against RSV for infants and children with cyanotic or acyanotic congenital heart disease who are less than 24 months of age at the time that therapy is begun." The addendum was based on results of a four-year clinical trial that demonstrated Palivizumab was safe and effective when used in infants and young children with both cyanotic and acyanotic congenital heart disease (CHD). The study was presented at the Cardiology Section of the American Academy Pediatrics (AAP) Conference, October 18, 2002 and published in the Journal of Pediatrics (2003;143:532-540). In September 2003, the FDA granted approval to expand the product label for the use of Palivizumab to young children with hemodynamically significant CHD.

In October 2003, the AAP issued a Policy Statement (<http://aappolicy.aappublications.org/cgi/reprint/pediatrics;112/6/1442.pdf>) regarding usage of Palivizumab for the prevention of RSV infection and provided revised recommendations for:

- Administering RSV prophylaxis to infants and children with CHD;
- Identifying infants with a history of preterm birth and chronic lung disease (CLD) who are most likely to benefit from immunoprophylaxis; and
- Reducing the risk of RSV exposure and infection in high-risk children.

The CCS program recognizes that there are a number of infants and children who may benefit from Palivizumab prophylaxis who do not meet the AAP Palivizumab criteria. One of the reasons for the differing criteria is due to the fact that the AAP is addressing all infants and children regardless of socioeconomic class. One of the factors that increase RSV disease severity is low socioeconomic status (Pediatric Infectious Disease Journal 1996; 15:1059-1068). Also, some children in their second and third year of life have chronic conditions that make them especially vulnerable to the adverse effects of an RSV infection. Because there are a small number of these children, it is unlikely that there will ever be a clinical trial to demonstrate the actual benefit of Palivizumab prophylaxis for this population. This numbered letter responds to the concern

that the guidelines allow some flexibility for CCS pediatric subspecialists to provide Palivizumab to patients whom they consider to be at uniquely high risk.

In addition, the CCS program has authorized Palivizumab for infants enrolled in the program who met the AAP Palivizumab criteria even if they did not have an eligible medical condition that would worsen or be complicated by an RSV infection. For example, CCS has authorized Palivizumab to a 5 month old infant born at 31 weeks gestation who's only CCS eligible condition was a clubfoot deformity. Although this congenital anomaly would not worsen with an RSV infection, the infant born at 31 weeks gestation was clearly at high risk for adverse events due to RSV infection. By authorizing Palivizumab in this example and in similar situations, CCS can help minimize delays in starting prophylaxis due to administrative concerns about the funding source.

### **III. POLICY**

- A. Palivizumab is a benefit for CCS clients, regardless of the eligible medical condition, who also meet one of the following criteria:
1. Children 24 months of age or younger at the start of RSV season with CLD requiring medical treatment (supplemental oxygen, bronchodilator, diuretic, corticosteroid, or other treatment) within six months before the anticipated start of the RSV season.
  2. Infants born at 28 weeks of gestation or earlier and who are less than 12 months of age at the start of RSV season.
  3. Infants born at 29 to 32 weeks of gestation who are less than six months of age at the start of RSV season.
  4. Infants born between 32 weeks and 35 weeks of gestation who are less than six months of age at the start of RSV season and who have two or more of the following risk factors:
    - Child care attendance
    - School-aged siblings
    - Exposure to environmental air pollutants (tobacco smoke, wood-burning stove, etc.)
    - Congenital abnormalities of the airways
    - Severe neuromuscular disease.

5. Children who are 24 months of age or younger at the start of RSV season with cyanotic or acyanotic CHD and the request for service is from the CCS approved Cardiac Special Care Center (SCC) or a cardiologist from a CCS approved Cardiac SCC, or the request is from a CCS approved pediatrician authorized in conjunction with a CCS approved Cardiac SCC or a CCS approved cardiologist from the Cardiac SCC.
6. Children with severe immunodeficiencies (e.g., severe combined immunodeficiency, acquired immunodeficiency syndrome, transplant recipients, or children who are immunocompromised due to chemotherapy) and the request for service is from a CCS approved Infectious Disease and Immunologic Disorder SCC, Transplant SCC, Hematology/Oncology SCC, or the request is from a CCS approved pediatrician authorized in conjunction with one of these CCS approved SCCs.
7. Children who are 48 months of age or younger at the start of RSV season who are at high risk of developing severe complications due to RSV infection and have one or more of the following conditions:
  - a. Respiratory system disease such as:
    - Cystic fibrosis
    - Chronic Lung Disease and requires oxygen therapy, noninvasive, or invasive ventilatory support
    - Pulmonary hypoplasia
    - Severe upper airway anomalies
    - A history of requiring mechanical ventilation the previous RSV season due to RSV disease
  - b. Hemodynamically significant cardiovascular system disease such as:
    - Pulmonary hypertension requiring medical therapy
    - Congestive heart failure requiring medication for control
    - Cyanotic heart disease
  - c. Children with neuromuscular conditions who have a poor cough due to weak or ineffective respiratory muscles and can not adequately clear respiratory secretions.

8. The CCS County or Regional Office Medical Consultant, after consulting with the CCS approved pediatric subspecialist may determine that an exception to criteria III.A.1-7 is medically justified. An example of an exception is clinical evidence, supported by medical literature, that the patient has a CCS medically eligible condition that would likely cause significant cardiopulmonary deterioration and hospitalization if the patient developed a RSV infection.
- B. For children who meet criteria III.A.1, 2, 3, 4 and 7, the request for service shall be from the CCS authorized pediatric subspecialist or CCS approved SCC; or the request shall be from a CCS approved pediatrician authorized in conjunction with a CCS approved pediatric subspecialist or CCS approved SCC.
- C. Premature infants who are currently only eligible for diagnostic services through the high-risk infant follow-up program are not eligible for authorization of Palivizumab.
- D. Palivizumab must be authorized as requested through the end of RSV season. For example, a CCS client who was born at 31 weeks and is five months old at the initial injection in November shall be authorized for injections for the entire RSV season.
- E. If an infant or child experiences a breakthrough RSV infection, prophylaxis should continue through the RSV season.
- F. Though it is preferred that the care of a CCS eligible infant/child be authorized to a CCS approved pediatrician in conjunction with a CCS approved pediatric subspecialist or CCS approved SCC, there are circumstances when there is no CCS approved pediatrician in an infant's/child's area of residence. In these circumstances references to "CCS approved pediatricians" in III.A.5 and 6, and in III.B., may be substituted with "CCS approved family practitioners". These family practitioners also need to be authorized in conjunction with a CCS approved pediatric subspecialist or CCS approved SCC.

#### **IV. POLICY IMPLEMENTATION**

Authorizations:

- A. Palivizumab requires separate authorization for outpatient administration. Palivizumab injections are administered monthly and may be authorized for up to a total of six injections over a six-month period of time (unless there is documentation by the requesting physician of longer need due to a lengthier RSV season).
- B. Palivizumab does not need a separate authorization for inpatient administration.
- C. Palivizumab is a Medi-Cal benefit. Please refer to "This Computes!" for the current method of authorizing Palivizumab.
- E. *Expedite Palivizumab authorizations to help ensure prompt initiation of protection from RSV for the infant/child and to prevent a lapse in protection, especially for the infant who will frequently receive the first injection in the hospital prior to discharge.*

If you have any questions regarding this numbered letter, please contact your state regional office medical consultant.

Sincerely,

**Original Signed by Marian Dalsey**

Marian Dalsey, M.D., M.P.H., Chief  
Children's Medical Services Branch